REMARKS

Claims 1-108 are pending, of which claims 47-108 are withdrawn from further consideration as being directed to a non-elected invention. The present Office Action addresses claims 1-46, rejecting all of the claims.

By this response, Applicants hereby amend claim 1 to recite that the scaffold material comprises a plurality of "regularly shaped close packed and interpenetrating voids, the material having a plurality of pores that interconnect the voids." Support for this limitation can be found at page 19, lines 5 and 6 of Applicants' specification. Claims 10-14 are amended to replace the term "cell" or "cells" with "void" or "voids," respectively. Support for this substitution can be found at page 19, lines 10-16, which paragraph is also amended herein to further clarify that the terms "cell" and "void" are synonymous. Accordingly, no new matter is added by these amendments.

Also, claims 1, 16, 17, 20-23, 26, 27, 35, 36, 39, 41, 44, and 46 are amended to remove ambiguities, provide proper antecedent basis for the limitations, and/or correct minor typographical errors. For example, claims 1, 16, 17, 20-22 and 24-26 are amended to change the phrase "cellular material" to "material." In addition, claims 3, 7-10, 13, 15, 16, 23-27, 31, 33, 36, 39, 41, 44, and 46 are amended to remove their multiple dependencies. In claim 17, Applicants amend the language to recite that "formation of the material includes a soft phase and hard phase." Claim 27 is further amended to recite that the scaffold is manufactured from a "reaction formulation" in order to provide antecedent basis for claims 35, 36, 39, 41, 44, and 46.

A detailed account of each of the amendments to the claims is discussed below.

For all of the following reasons, Applicants respectfully request reconsideration of the present application.

Introductory Remarks

Applicants note with appreciation the Examiner's acknowledgment of the entries of the Secondary Preliminary Amendment and the Replacement Formal Drawings that were previously submitted.

35 U.S.C. §112 rejections

In the present Office Action, the Examiner initially rejects claims 1-46 pursuant to 35 U.S.C. §112, 2nd paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The following is a detailed outline of the amendments made herein to address each of the Examiner's concerns.

With respect to claim 1, the Examiner regards the term "cellular material" as rendering the claim indefinite. Applicants hereby adopt the Examiner's suggestion to amend claim 1 to remove the word "cellular" in each instance where the term "cellular material" appears, in order to avoid confusion. For consistency, these amendments are also made to dependent claims 16, 17, 20-22, and 24-26.

With regard to claims 3, 7-10, 13, 15, 16, 23-27, 31, 33, 36, 39, 41, 44, and 46, each of these claims is amended to remove its multiple dependency.

Claims 10-14 are considered unclear by the Examiner by "requiring or further limiting cells or a cell and not having antecedent basis for the scaffold of claim 1 containing cells in addition to the voids and pores required." By this amendment, the

term "cell" or "cells" in claims 10-14 is replaced with the term "void" or "voids," respectively. These substitutions are made to correct the typographical errors contained therein. Applicants believe the term "cell" was inadvertently used to reference the voids that make up the scaffold's cellular material (i.e., the scaffold's porous polymeric material for supporting cellular growth) without further clarifying that the terms "cell" and "void" are synonymous. Applicants have amended the specification at page 19, lines 1-16 for consistency and also to more clearly define this relationship .

With respect to claims 16 and 23, the Examiner objects to the term "solubility parameter" and "cohesive energy density." Applicants respectfully submit that these terms are well known in the art and not indefinite. The broader term, "solubility parameter," refers to numerical methods of predicting the extent of interaction between materials, particularly between liquids and molecules. The term "cohesive energy density" refers to the cohesive energy per unit volume of a material, the energy being the potential or internal energy of molecules in a condensed phase. In other words, the solubility parameter is a numerical value that indicates the relative solvency behavior of a specific solvent, which value is derived from the cohesive energy density of the solvent. Both these concepts are expressed in units of MPa's (mega pascals or 1 million pascals), and their definitions can be found in general polymer chemistry textbooks.

Regarding claim 17, Applicants amend the claim to recite that "formation of the material includes a soft phase and hard phase" to clarify the ambiguity in the language.

The Examiner objects to claims 18 and 19 for containing the term "polar ratio." Applicants submit that the definition of polar ratio can clearly be found at page 23, line

27 through page 24, line 5 in Applicants' specification. Accordingly, there is no uncertainty as to the claims' meaning and scope. Further, the Examiner objects to the phrase "the polymer" as lacking antecedent basis. However, it is implicit that the recitation of "polyurethane," a polymer, in claim 1 provides the proper antecedent basis for these terms.

Regarding claims 22 and 23, claim 22 is amended to correct a typographical error and replace the term "hard segment context" with "hard segment ***content***," while claim 23 is amended to replace the phrase "the cohesive energy density" with "***a*** cohesive energy density" to provide proper antecedent basis.

Claim 24 is amended to replace the phrase "the leachables content" with "***a*** leachables content" to provide proper antecedent basis for this limitation.

Applicants adopt the Examiner's helpful suggestion in claim 27 and amend the language to recite "4,4 diphenyl methane diisocyanate (MDI) containing a 2,4 diphenyl methane diisocyanate isomer" for consistency. Claim 27 is further amended to recite that the scaffold is manufactured from a "reaction formulation" to provide proper antecedent basis for this limitation in claims 35, 36, 39, 41, and 46.

With respect to claims 35, 36 and 44-46, Applicants submit that the term "mass" is properly used in these instances. The Examiner is kindly referred to page 44, lines 16-18 of Applicants' specification which refer to the percentage content by mass and not weight.

Finally, regarding claims 39 and 40, the Examiner objects to the recitation of "the isocyanate index" as lacking antecedent basis. Claim 39 is amended to now recite "***an*** isocyanate index" to remove this ambiguity.

Applicants believe that each and every 35 U.S.C. §112, 2nd paragraph rejection cited in the Office Action has been address fully by these amendments. Accordingly, the Examiner is asked to kindly remove the indefiniteness rejections over claims 1-46.

The Prior Art Rejections

The Examiner rejects claims 1-26 and 39-46 pursuant to 35 U.S.C. §103(a) as being unpatentable over Brady et al. (U.S. Patent No. 6,177,522), in view of Holy et al. (U.S. Patent No. 6,379,962), and if necessary further in view of Agrawal et al. (U.S. Patent No. 6,187,329), Brekke (U.S. Patent No. 4,186,448), or Barrows et al. (U.S. Patent No. 5,856,367). Claims 27, 28, 31-36, and 39-46 are rejected over the same combination of references, and further in view of the combination of Hanson (U.S. Patent No. 4,687,482) and Tabor (U.S. Patent No. 5,479,867), or the combination of Reich et al. (U.S. Patent No. 5,993,972) and Tabor. Finally, claims 37 and 38 are rejected over the same combinations of references above, and further in view of Jamiolkowski et al. (U.S. Patent No. 6,147,168).

Applicants respectfully disagree, and kindly request reconsideration and withdrawal of these rejections in view of the following remarks.

The Prior Art does not Satisfy the Claimed Invention

As amended, claim 1 recites:

> A tissue engineering scaffold for cell, tissue or organ growth comprising a biocompatible porous polyurethane material comprising a plurality of regularly shaped close packed and interpenetrating voids, the material having a plurality of pores that interconnect the voids, the material further having a void content from 85% to 98% and a surface area to volume ratio of from 5 to 400 mm^2/mm^3.

Turning now to the cited prior art, the Examiner relies on Brady et al. (U.S. Patent No. 6,177,522) as his primary reference, and Holy et al. (U.S. Patent No. 6,379,962), Agrawal et al. (U.S. Patent No. 6,187,329), and Barrows et al. (U.S. Patent No. 5,856,367), either alone or in combination, as secondary references to reject claims 1-26 and 39-46. Applicants respectfully disagree.

Brady et al. is generally directed to a polycarbonate urethane polymer foam useful for long term implantation, and methods for its manufacture. The polycarbonate urethane, or polyurethane, foam is biostable and prepared by a reaction of an isocyanate, a polycarbonate and a chain extender (see, col. 2, lines 49-58). Once formed, the foam can be cut to a desired shape and used in medical applications, such as for a vessel occluder. The open structure of the foam enables collapsibility, compressibility, and allows for tissue infiltration (*See,* col. 4, lines 52-67). However, Brady et al. does not specifically disclose or suggest the formation of a polyurethane material which has a very high void content of from 85% to 98% and a surface area to volume ratio of from 5 to 400 mm^2/mm^3, as is required of the claimed invention. Nor does Brady et al. disclose or suggest that the polyurethane material comprise a plurality of regularly shaped close packed and interpenetrating voids, the material having a plurality of pores that interconnect the voids, as is also required of the claimed invention.

In order to compensate for this deficiency, the Examiner asserts that one of ordinary skill in the art could combine the teachings of Brady et al. with Holy et al., Agrawal et al., Brekke, and/or Barrow et al. to achieve the claimed invention. Applicants respectfully disagree. None of the secondary references teaches a biocompatible

porous polyurethane material comprising a plurality of regularly shaped close packed and interpenetrating voids, the material having a plurality of pores that interconnect the voids, the material further having a void content from 85% to 98% and a surface area to volume ratio of from 5 to 400 mm^2/mm^3, as is required of the claimed invention.

Moreover, Brekke teaches in col. 7, lines 10-19 that the polymeric implant comprises "randomly positioned, randomly shaped and sized voids," which is in clear contrast to Applicants' scaffold comprising ***regularly shaped*** close packed and interpenetrating voids. Thus, Brekke teaches away from Applicants' claimed invention; its combination with Brady et al. would not satisfy the claimed invention, nor would the combination be obvious to one having ordinary skill in the art.

With respect to Holy et al., Agrawal et al., and Barrows et al., none of these references teach a polymer material having a surface area to volume ratio of from 5 to 400 mm^2/mm^3, as is required of the claimed invention. As clearly discussed above, this high surface area provides Applicants' polyurethane material with the properties to enable better cellular growth therethrough. This high surface area is not taught anywhere in any of the cited references. Contrary to the Examiner's assertions, this high surface area property is not inherent in the secondary references. Porosity is determined by calculating void volume per total volume (i.e., cubic units divided by cubic units); the surface area ratio is determined by looking at the surface area per total volume. It does not follow that a porous material having the same porosity as Applicants' claimed invention would also inherently have the same surface area per unit volume, as the Examiner asserts. Accordingly, Applicants submit that the combination of Brady et al. with any of these secondary references (either alone or in combination),

all of which are silent as to the surface area ratio required of claim 1, would fail to satisfy the claimed invention.

Because the combination of Brady et al. with either Holy et al., Agrawal et al., Brekke, and/or Barrow et al. fails to substantially disclose the claimed invention, Applicants submit that their combination with either Hanson (U.S. Patent No. 4,687,482), Tabor (U.S. Patent No. 5,478,867), Reich et al. (U.S. Patent No. 5,993,972), or Jamiolkowski et al. (U.S. Patent No. 6,147,168) would still not overcome the deficiencies in the Examiner's case-in-chief. This is because neither Hanson, Tabor, Reich et al., or Jamiolkowski et al. disclose or suggest a biocompatible porous polyurethane material comprising a plurality of regularly shaped close packed and interpenetrating voids, the material having a plurality of pores that interconnect the voids, the material further having a void content from 85% to 98% and a surface area to volume ratio of from 5 to 400 mm^2/mm^3, as is required of the claimed invention.

For all of the above reasons, Applicants submit that the prior art fails to anticipate or render obvious the claimed invention because their combination fails to satisfy each and every limitation of the claimed invention. The Examiner is kindly asked to reconsider and withdraw the prior art rejections over claims 1-46.

The Double Patenting Rejections

Applicants will be filing a Terminal Disclaimer to overcome the obviousness-type double patenting rejection of claims 1-46 over U.S. Patent No. 6,177,522.

Applicants respectfully request that the Examiner hold the requirement for a Terminal Disclaimer in abeyance until such time as the claims in this application are

indicated as being allowable such that the respective status of each of the claims can be properly considered.

Information Disclosure Statement

Applicants wish to bring the Examiner's attention to the Information Disclosure Statement (IDS) submitted along with this response. The IDS cites published International Application No. WO99/24084, which corresponds to U.S. Patent No. 6,177,522 and published on May 20, 1999. Applicants do not believe this reference raises any new issues related to patentability because the reference does not fairly describe a tissue engineering scaffold as claimed.

Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: September 16, 2004

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